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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,722	EATON ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-9,11-13 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-9,11-13 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/15/2005 has been entered. Claims 7–9, 11–13 and 17–20 are pending and being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC §§ 101, 112

Claims 7–9, 11–13 and 17–20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants' discussion of the utility legal standard is acknowledged. However, the present rejection is based upon Applicants' failure to disclose to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. Adopting Applicants' standard for utility would result in a per se rule that any disclosed difference in mRNA expression is significant, relevant, and tumor-dependent and that any such difference would require a per se rule of utility for the polynucleotide, the encoded polypeptide and antibodies thereto. The examiner declines to attenuate the utility requirement to this degree because this standard is not what the art teaches. The countervailing evidence shows that the skilled artisan would not know if the disclosed change in PRO3579 transcripts is tumor-dependent or tumor-independent. See Hu (J Proteome

Res. 2003 Jul-Aug;2(4):405-12), of record. A tumor-independent detection of a change in mRNA expression cannot be used as a tumor marker. The skilled artisan would not know if or how expression of the PRO3579 polypeptide would change in tumors because there are numerous levels of control of protein synthesis, degradation, processing and modification, which are only apparent by direct protein analysis. See Haynes (Electrophoresis. 1998 Aug;19(11):1862-71) and Hancock (J Proteome Res. 2004 Jul-Aug;3(4):685), both of record. Even if one were to assume that the disclosed change in PRO3579 transcripts could reasonably be correlated with an assumed change in PRO3579 polypeptide expression the skilled artisan still would not know if the assumed change in PRO3579 polypeptide expression is tumor-dependent or tumor-independent because it is unknown if the disclosed change in PRO3579 transcripts is tumor-dependent or tumor-independent.

The examiner is aware that the present claims are drawn to polynucleotides. However, the only apparent use of the claimed degenerate polynucleotides, vectors and host cells is in the production of the encoded polypeptide. The specification discloses:

> Host cells are transfected or transformed with expression or cloning vectors described herein for PRO production ... . Page 79, paragraph 0292.

It is therefore appropriate to consider the utility of the encoded polypeptide in relation to the claimed degenerate polynucleotides, vectors and host cells. A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility or a method of making a material that itself has no specific, substantial and credible utility are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define substantial utilities. Neither the specification nor any of Applicants' arguments, exhibits, declarations or other evidence

provide any specific data disclosing if or how PRO3579 polypeptide expression changes in tumor tissue. Instead, Applicants rely on a general correlation between mRNA expression and expression of the encoded protein rather than the specific correlation between PRO3579 transcripts and PRO3579 polypeptide expression to argue that it is more likely than not that a change in PRO3579 transcripts is correlated with an assumed change in PRO3579 polypeptide expression. Without any evidence of the expression of PRO3579 in tumor tissue this argument is of no avail to Applicants.

Because Applicants have failed to validate the significance of PRO3579 gene expression to melanoma tumors and have failed to establish the correlation between PRO3579 mRNA expression and PRO3579 polypeptide expression in melanoma tumors, Applicants have failed to establish a significant probability that the PRO3579 gene, polypeptide and antibodies are useful as a cancer diagnostic or therapeutic. The specification lacks a sufficient correlation between the test performed on PRO3579 mRNA expression and the asserted utility of the PRO3579 polynucleotide and polypeptide. There is no reason for the skilled artisan to believe that it is more likely than not that the PRO3579 polynucleotide, polypeptide and antibodies could be used as a cancer diagnostic or therapeutic. The asserted utility of the PRO3579 gene, polypeptide and antibodies would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Regarding the requirement for further experimentation as a basis for lack of utility, utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities (M.P.E.P. § 2107.01 I). In the present case, the asserted diagnostic or therapeutic utilities of the PRO3579 gene, polypeptide and antibodies would require or constitute carrying out further research to

identify or reasonably confirm a "real world" context of use because the skilled artisan would not know if the reported change in PRO3579 gene expression was tumor-dependent or tumor-independent and would not know if or how PRO3579 polypeptide expression would change in tumors.

Unlike the situation wherein a claimed compound has been tested and has shown a pharmacological activity and therefore has a therapeutic utility sufficient under the patent laws, in the present situation Applicants' have not provided any testing of the expression of the PRO3579 polypeptide. In the absence of any information on the role, activity, or expression of the PRO3579 polypeptide in cancer, the examiner therefore considers the asserted utilities to not be specific and substantial because the skilled artisan would not know if the reported change in PRO3579 transcripts is tumor-dependent or tumor-independent and would not know if or how PRO3579 polypeptide expression would change in cancer. Although the asserted utility may be specific to the claimed invention, it is not substantial. Therefore, the claimed invention lacks a specific and substantial asserted utility.

Applicants' utility standard would mandate only a showing that it is "not implausible" that the invention will work for its intended purpose. If mere plausibility were the test for how to use a claimed invention, applicants could obtain patent rights to "inventions" based on a disclosure consisting of little more than guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor disclose how to use an invention rather than merely proposing an unproved hypothesis. As set forth in *Brenner v. Manson*:

> But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. "[A] patent system must be related to the world of commerce rather than to the realm of philosophy."

The examiner concludes that Applicants' have failed to disclose how to use the claimed invention.

Applicants cite Mijalski (Proc Natl Acad Sci U S A. 2005 Jun 14;102(24):8621-6) and Mootha (Cell. 2003 Nov 26;115(5):629-40) as more relevant and recent evidence that mRNA levels correlate with protein expression. Applicants' arguments have been fully considered but they are not persuasive. Mijalski studies transcriptional versus translational regulation (page 8625, left column and paragraph bridging pages 8625-8626). The conclusion is that "The comparative analysis suggests correlation between transcriptional and translational expression for the majority of genes. Significant exceptions from this correlation confirm the complementarities of both approaches." See the abstract. Mijalski also acknowledges that the proteome of a cell is the result of controlled biosynthesis and, therefore, is largely (but not exclusively) regulated by gene expression (page 8621, left column, full paragraph 1). However, the fact that there may be a general correlation between transcriptional and translational expression for the majority of the genes does not establish the correlation between the change, if any, in PRO3579 transcripts and PRO3579 polypeptide expression in tumors because there are examples of genes for which such a correlation does not exist and because the proteome of a cell is not exclusively regulated by gene expression, as evidenced by Mijalski. Mootha studies concordance of mRNA abundance and protein detection (page 633, section bridging left and right columns). The conclusion is that "Hence, on a bulk level, mRNA expression levels are indeed correlated to detection by proteomics. The fully discordant cases may represent genes whose mRNA and protein products

are regulated via posttranscriptional mechanisms, although some may reflect noise in the measurements." The fact that mRNA expression levels are correlated to detection by proteomics on a bulk level does not establish the correlation between the change, if any, in PRO3579 transcripts and PRO3579 polypeptide expression in tumors because there are discordant cases, as evidenced by Mootha.

Applicants refer to a declaration of Dr. Polakis filed with the response. The declaration under 37 CFR 1.132 filed 08/15/2005 is insufficient to overcome the rejection of claims 7–9, 11–13 and 17–20 based upon a lack of utility as set forth in the last Office action because: The facts to be established are whether or not the disclosed change in PRO3579 transcripts is disease-dependent or disease-independent and whether or not there is a correlation between the reported change in PRO3579 transcripts and a change in PRO3579 polypeptides levels in tumors as compared to their normal tissue counterparts. The declaration does not provide any data concerning PRO3579 mRNA expression, PRO3579 polypeptide expression, or the correlation between the two in tumor tissue, normal tissue, or any other type of tissue sample. There is no evidence of record that either the PRO3579 polynucleotide or the PRO3579 polypeptide were abundantly expressed. The present specification does not teach the level of reproducibility or reliability of the results seen in Example 18. Given the paucity of information regarding PRO3579 expression in tumors and the evidence in the art that there are numerous levels of control of protein synthesis, degradation, processing and modification, which are only apparent by direct protein analysis, one skilled in the art would not know if the change in PRO3579 mRNA expression was disease-dependent or disease-independent and would not know if or how PRO3579 polypeptide expression would change in tumors. Even if the examiner were to assume

that the disclosed change in PRO3579 transcripts could reasonably be correlated with an assumed change in PRO3579 polypeptide expression, it still could not be ascertained if the assumed change in PRO3579 polypeptide expression would be disease-dependent or disease-independent because it is unknown if the change in PRO3579 transcripts is disease-dependent or disease-independent. While Dr. Polakis refers to his experiments, only conclusions were set forth in the declaration. No data or results were presented for independent analysis. Even if the examiner were to accept Dr. Polakis' conclusion, it still would be considered evidence that the skilled artisan would not know if or how PRO3579 polypeptide expression would change in cancer because 20% of the cases examined do not show a correlation, according to Dr. Polakis. The fact that there may be a commonly understood general rule or dogma that increased mRNA levels are predictive of corresponding increased levels of the encoded protein does not establish the correlation between the change, if any, in PRO3579 transcripts and PRO3579 polypeptide expression in tumors because there are examples of genes for which such a correlation does not exist, according to Dr. Polakis.

The examiner is not requiring that a change in the level of a particular mRNA must always be correlated with a corresponding change in the level of the encoded protein. The examiner is not arguing that there is no positive correlation between a change in the level of a particular mRNA with a change in the level of the encoded protein. The examiner is arguing that the change in PRO3579 transcripts must be tumor-dependent and there must be a corresponding change in the level of the PRO3579 polypeptide in order for the skilled artisan to use the PRO3579 polynucleotide and polypeptide as the asserted diagnostic. Neither the specification nor any of Applicants' arguments, exhibits, declarations or other evidence provide any specific

data disclosing if or how PRO3579 polypeptide expression changes in tumors. Instead, Applicants rely on a general correlation between mRNA expression and expression of the encoded protein without any evidence of the expression of the PRO3579 polypeptide in normal tissue or tumor tissue. In effect, Applicants' position is that PRO3579 transcript levels are the sole determinant of PRO3579 levels. The specification fails to provide any testing of PRO3579 polypeptide levels. The inherent lack of certainty in this general correlation results in a failure to prove practical utility for the PRO3579 polypeptide and antibodies.

Claims 7–9, 11–13 and 17–20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it. As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection set out a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. A 35 U.S.C. 112, first

paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

Claims 7 and 17–20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' amendment to the claims and request to withdraw this rejection is acknowledged. The claims are directed to or encompass the genus of all nucleic acid molecules having a recited % identity to a nucleic acid molecule within the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 102. The examiner has been and is aware that the present claims are drawn to polynucleotides. However, the only apparent use of the claimed degenerate polynucleotides, vectors and host cells is in the production of the encoded polypeptide. The specification discloses:

> Host cells are transfected or transformed with expression or cloning vectors described herein for PRO production ... . Page 79, paragraph 0292.

It is therefore appropriate to consider the enablement of the encoded polypeptide in relation to the claimed degenerate polynucleotides, vectors and host cells. There is no functional limitation to the encoded polypeptides. No information is provided in the specification regarding the occurrence of these degenerate, variant polynucleotides or the polypeptides they encode. To the extent that Applicants rely on a central dogma, a significant probability, or reasonable correlation as discussed in their reply to the utility rejection, these arguments have been fully considered but they are not persuasive for the same reasons that they were not persuasive in the rejection for

lack of utility. Specifically, Haynes and Hancock, as discussed above, provide evidence that the skilled artisan would not know if or how PRO3579 polypeptide expression would change in melanoma tumor. This conclusion is supported by the declaration of Dr. Polakis under 37 CFR 1.132 filed 08/15/2005:

> "... there have been published reports of genes for which such a correlation does not exist, ..." (paragraph 6).

Even if the examiner were to assume that the change in PRO3579 transcripts could reasonably be correlated with a change in PRO3579 polypeptide expression, it still could not be ascertained if the assumed change in PRO3579 polypeptide expression would be disease-dependent or disease-independent because the skilled artisan would not know if the change in PRO3579 transcripts is disease-dependent or disease-independent. No information is provided in the differential analysis of PRO3579 polynucleotide expression regarding the level of expression, activity, or role in cancer of the PRO3579 polypeptide. In the absence of this information a skilled practitioner would have to resort to a substantial amount of undue experimentation in the form of characterization of the PRO3579 polypeptide and validation of its association with tumors.

Even in cases where genes are differentially expressed in a cancer and overexpression of the corresponding protein products in the cancer is verified, the art indicates that further experimentation is necessary to establish the usefulness of these genes and gene products for diagnosis, prognosis, and treatment of cancer. For example, Yousef (Cancer Res. 2003 May 1;63(9):2223-7) indicates that many members of the human kallikrein (KLK) gene family are differentially regulated in ovarian cancer and have potential as diagnostic and/or prognostic markers. Yousef performed *in silico* analyses of the expression pattern of the 15 human KLK genes in normal and cancerous ovarian tissues and cell lines. Yousef found that seven KLK

genes (KLK5, KLK6, KLK7, KLK8, KLK10, KLK11, and KLK14) are up-regulated in ovarian cancer. Yousef experimentally verified the overexpression of six KLK proteins in cancer versus normal or benign tissues with highly sensitive and specific immunofluorometric assays. A statistically significant stepwise increase in protein levels was found among normal, benign, and cancerous ovarian tissues. The expression of five KLKs showed a strong degree of correlation at the protein level, suggesting the existence of a common mechanism or pathway that controls the expression of this group of adjacent genes during ovarian cancer progression. See the Abstract. However, Yousef indicates that further experimentation is necessary to establish the usefulness of these KLKs for diagnosis, prognosis, and treatment of ovarian cancer (page 2226, right column, last paragraph). Yousef, which discloses more about a potential cancer diagnostic, prognostic, or treatment than the present specification discloses about PRO3579, indicates that the skilled artisan would have to engage in a substantial amount of undue experimentation in the form of characterization of the claimed polynucleotides and the polypeptides they encode and validation of their association with tumors in order to determine if the claimed polynucleotides and the polypeptides they encode could be used as a cancer diagnostic. It is this additional characterization of that single disclosed example of PRO3579 mRNA expression that is required in order for the skilled artisan to obtain the information necessary to practice the full scope of the claimed invention that constitutes undue experimentation. Therefore, there is insufficient disclosure to teach those of skill in the art how to make and use the invention as broadly as it is claimed without undue experimentation.

Claims 7 and 17–20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' amendment to the claims is acknowledged and request to withdraw this rejection is acknowledged. The claims are directed to or encompass the genus of all nucleic acid molecules having a recited % identity to a nucleic acid molecule within the genus of all nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 102. The claims do not require that the polynucleotides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by some level of sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity or hybridization. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides encoding polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 102, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that they may claim smaller fragments without violating the written description provision of 35 U.S.C. § 112, first paragraph. Applicants' arguments have been fully considered but they are not persuasive. The claim is directed to or encompasses a polynucleotide encoding a polypeptide consisting of amino acids 109-353 of SEQ ID NO: 102. The present specification describes an isolated PRO polypeptide, comprising an amino acid sequence having at least about a recited percent identity to an extracellular domain of a transmembrane protein or any other specifically defined fragment of the full-length amino acid sequence (page 8, paragraph 0014). However, the specification does not specifically define the 109-353 fragment of SEQ ID NO: 102 nor does the specification define the 109-353 fragment of SEQ ID NO: 102 as an extracellular domain. Therefore, reciting "amino acids 109-353 of the polypeptide" changes the meaning, scope or content of the original disclosure, which raises the issue of new matter.

New Formal Matters, Objections, and/or Rejections:

Claim Objections

Claims 8 and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The polynucleotide of claims 8 and 9 does not consists

of a nucleic acid sequence 95% identical to a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 102.

Claims 12 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The polynucleotide of claims 12 and 13 does not consists of nucleotides 200 to 1720 of SEQ ID NO: 101.

Claim Rejections - 35 USC § 112

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for the limitation "nucleotides 200 to 1720" cannot be found in the disclosure as originally filed and Applicants do not indicated where this amended is supported by the original disclosure. Therefore, this limitation is new matter.

Conclusion

No claims are allowable.

This Office action has an attached requirement for information under 37 CFR 1.105. A complete reply to this Office action must include a complete reply to the attached requirement for information. The time period for reply to the attached requirement coincides with the time period for reply to this Office action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMBO
PRIMARY EXAMINER
ART UNIT 1647

DSR
DECEMBER 26, 2005

Requirement For Information Under 37 CFR 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

This requirement is necessary for determining if there are any issues under 35 U.S.C. § 102(f) related to patentability of the presently claimed invention.

Applicants refer to the Incyte EST "sequence" in the response filed 08/15/2005. A DNA "sequence" is merely descriptive of the linear order of monomers of which a DNA molecule is made and is not a DNA molecule. In U.S. Application No. 60/170,262 it is disclosed that Applicants purchased Incyte EST clone no. 2377329 and the cDNA insert was obtained and sequenced. The sequence of this cDNA insert is shown in Figure 1 and is designated as DNA68862-2546. Figure 1 in U.S. Application No. 60/170,262 appears to be identical to figure 101 of the present application. Furthermore, the present application designates SEQ ID NO: 101 as "DNA68862-2546" (paragraph 0128).

From the evidence provided it cannot be determined if the "sequence" referred to by applicants is a partial sequence of the cDNA insert or if it is the complete and entire sequence of the cDNA insert in the purchased clone. .

In response to this requirement, please provide information regarding:

1. the complete and entire sequence of the cDNA insert in the purchased clone;
2. the percent identity of the complete and entire sequence of the cDNA insert in the purchased clone to the sequence of the coding region of SEQ ID NO: 101;
3. whether the purchased clone comprises a vector;
4. whether the cDNA insert in the purchased clone is operably linked to control sequences recognized by any host cell transformed with said clone, and if so do the control sequences comprise a eukaryotic and/or prokaryotic promoter;
5. whether the purchased clone was double stranded DNA; and,
6. whether the purchased clone was provided to Applicants in a host cell, and if so was the host cell a CHO cell, an E. coli or a yeast cell

The applicant is reminded that the reply to this requirement must be made with candor

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER